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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,256	04/17/2006	Fung-Lung Chung	11015-008	4893
29847	7590	10/12/2007		
Beusse Wolter Sanks Mora & Maire 390 N. ORANGE AVENUE SUITE 2500 ORLANDO, FL 32801			EXAMINER STONE, CHRISTOPHER R	
			ART UNIT 4173	PAPER NUMBER
			MAIL DATE 10/12/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/541,256

Applicant(s)

CHUNG ET AL.

Examiner

Christopher R. Stone

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 15-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1 page.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I in the reply filed on October 2, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 15-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. The requirement to elect a single disclosed species of isothiocyanate conjugate has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-6, 9 and 12 are rejected under 35 U.S.C. 102(a) as being anticipated by Hecht et al.

Claims 1-6, 9 and 12 are drawn to a method of inhibiting lung tumorigenesis in a mammal in need thereof, comprising administering to said mammal an effective amount of a conjugate of an isothiocyanate at the post-

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initiation stages of tumor growth. Post-initiation stage is defined in the specification as any time period after exposure to a carcinogen.

Hecht et al discloses a method of inhibiting lung tumorigenesis in a mouse, comprising the oral administration of an isothiocyanate conjugate (PEITC-NAC) at the post-initiation stages of tumor growth (p. 1456, column 2, paragraph 2; Fig. 2; Table II, groups 5, 11 and 14). The tumors are inherently malignant or non-malignant, since all tumors belong to one of these two categories.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 7, 8, 10, 11, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hecht et al.

In addition to the aforementioned teachings, Hecht et al discloses that lung cancer is the most common cancer in the world and the leading cause of cancer death in the United States. Smokers and ex-smokers are disclosed as high-risk for the development of lung cancer. Furthermore, Hecht et al teaches that there are no chemopreventative agents with proven efficacy in humans and that the goal of their research is to identify and develop such agents.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use the method of Hecht et al to inhibit tumorigenesis in human smokers and ex-smokers, since lung cancer is so prevalent in this patient population, thus resulting in the practice of the instantly claimed invention with a reasonable expectation of success.

It would have been obvious to one of ordinary skill in the art to accomplish oral administration using a tablet or capsule dosage form. Tablets and capsules are commonly used oral dosage forms in the pharmaceutical formulation art.

The optimization of the dosage amount and schedule would have been obvious to one of ordinary skill in the art at the time of the invention to determine the regimen with maximum efficacy. This routine experimentation is common in the pharmaceutical art. Applicant is reminded of in re Aller, which affirmed that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine

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experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)

Claim Objections

Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 12 is drawn the method of claim 1 wherein the tumor growth is malignant or non-malignant. All tumors are either malignant or non-malignant; therefore claim 12 fails to further limit the tumor of claim 1.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Jiao et al 'Chemopreventative activity of thiol conjugates of isothiocyanates for lung tumorigenesis'

Carcinogenesis, 18(11), p. 2143-2147, 1997.

This reference teaches the use of thiol conjugates of isothiocyanates, including PEITC-NAC, for the inhibition of lung tumorigenesis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Stone whose telephone number is (571) 270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

10October2007
CRS


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER